SEP - 7 2001

Cordis Europa N.V.,
a Johnson & Johnson company

Special 510(k) Premarket Notification

K012590

Attachment 1

Summary of Safety and Effectiveness

Submitter:

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Date prepared

09 August 2001.

General provisions

Trade name: Cordis **PALMAZ® GENESIS™ Transhepatic Biliary Stent on OPTA™ PRO .035" Delivery System**.

Common Name: Biliary stent and accessories

Classification Name: 21 CFR 876.5010 Biliary Catheter and accessories.

Device Classification

Class II.

Name of predicate device(s)

- Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent (ref. K012090)
- Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent on SLALOM .018 Delivery System (ref. K012056)
- Cordis OPTA ™ PRO (formerly known as OPTA LP) PTA Balloon Catheter (ref. K971448, K981407, K991028)

Performance standards

Performance standards have not been established for this device by the FDA under section 514 of the Food, Drug and Cosmetic Act.

Device Description

The PALMAZ GENESIS Transhepatic Biliary Stent is a balloon-expandable, laser cut stent made from 316L Stainless Steel tubing. The stent is sold mounted on a Cordis percutaneous transluminal angioplasty (PTA) balloon catheter. The stent is provided in nominal, unexpanded stent lengths from 19 to 79 mm. The stent is designed for expansion to diameters from 8 to 10 mm, depending on the diameter of the associated balloon upon which it is mounted.

The Cordis OPTA PRO PTA balloon catheter, formerly known as the OPTA LP PTA Balloon Catheter, is used as a delivery system for the PALMAZ GENESIS Transhepatic Biliary Stent. The delivery system utilizes an over-the-wire design and is a catheter with a distal DURALYN™ balloon and a proximal Y-connector. Two radiopaque marker bands aid in stent placement. The injectate lumen (marked "THRU") is used to inject contrast medium via hand injection, and to track the catheter over a guide wire. The inflation lumen (marked "BALLOON") is used to inflate and deflate the balloon. The nominal balloon size is printed on the Y-connector.

A metal introducer tube is included in the packaging.

The PALMAZ GENESIS Transhepatic Biliary stent on OPTA PRO .035" Delivery System is provided sterile (via ethylene oxide) and is intended for single use only.

Intended Use

The Cordis PALMAZ GENESIS Transhepatic Biliary Stent on OPTA PRO .035" Delivery System is indicated for use in the palliation of malignant neoplasms in the biliary tree.

Performance Data

The safety and effectiveness of the Cordis PALMAZ GENESIS Transhepatic Biliary Stent on OPTA PRO .035" Delivery System have been demonstrated via data collected from non-clinical design verification tests and analyses.

A statement of substantial equivalence to another product is required by 21 CFR 807.87 and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the commissioner of the FDA stated: "A determination of substantial equivalence under the Fedral Food, Drug and Cosmetic Act releted to the fact that the product can be lawfully marketed without pre-market approval or reclassification. The determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Federal Register 42, 50 et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 7 2001

Cordis Corporation
Cordis Europa, N.V.
c/o Mr. Charles J. Ryan, RAC
Manager, Regulatory Affairs
7 Powder Horn Drive
WARREN NJ 07059

Re: K012590
Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent
on OPTA™ PRO .035" Delivery System
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: August 9, 2001
Received: August 10, 2001

Dear Mr. Ryan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K012590

Device Name: Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent on OPTA™ PRO .035" Delivery System

FDA's Statement of the Indications For Use for device:

The Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent on OPTA™ PRO .035" Delivery System is indicated for the palliation of malignant neoplasms in the biliary tree.

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012590

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)